Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the effect of Rhus Coriaria on pain and size of oral recurrent aphtus stomatitis in patients reffered to Shiraz Dental School

Protocol summary

Study aim

The aim of this study is evaluating the effect of somaq on size and pain of patients with recurrent aphtus stomatitis.

Design

22 patients with active RAS will be divided randomly (block randomization) to 2 experimental and control group.

Settings and conduct

This randomized phase 2 clinical trial will be done in 2017 on the patients who will be referred to Shiraz Dental School for their RAS. In experimental group 11 patients will receive somaq pills but in the control group oral paste triadent0.1 three times in a day will be used by 11participents. In the experimental group the patients will use 3pills daily for 7days.The researcher will evaluate VAS (visual analogue scale) of participants before and after using pills (on day 0,1,2,3,4,5,6,7). The size of a specific ulcer in each patient also will be measured by graded tongue blade on day 0,1,2,3,4,5,6,7. The healing process will be evaluated by measuring oral ulcer size and patient pain will be studied by VAS.

Participants/Inclusion and exclusion criteria

The patient with RAS since less than 72h will be enrolled in this research. They should have not use any topical or oral corticosteroid since a month before. Also they should not use any analgesic mouthwash or systemic analgesic since 3 days before this evaluation. The participant who will sign the written consent form will be recruited.

Intervention groups

In experimental group 11 patients will receive somaq pills but in the control group oral paste triadent 0.1 three times in a day will be used by 11participents. In the experimental group the patients will use 3 pills daily for 7days.

Main outcome variables

level of pain; size of lesion

General information

Reason for update

Acronym

recurrent aphtus stomatitis (RAS)

IRCT registration information

IRCT registration number: **IRCT20120101008585N4**
Registration date: **2017-12-24, 1396/10/03**
Registration timing: **registered_while_recruiting**

Last update: **2017-12-24, 1396/10/03**
Update count: **0**

Registration date

2017-12-24, 1396/10/03

Registrant information

Name
Fatemeh Lavaee
Name of organization / entity
Shiraz Dental School
Country
Iran (Islamic Republic of)
Phone
+98 71 1631 9309
Email address
lavaeef@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation the effect of Rhus Coriaria on pain and size of oral recurrent aphtus stomatitis in patients reffered to Shiraz Dental School

Public title
Evaluation the effect of Rhus Coriaria on oral aphtus stomatitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having recurrent aphtus stomatis not using other routine prescribed medication for RAS during evaluation less than 72 hour from emerging of the lesion not using systemic or topical corticosteroid since 1 month ago Patient more than 6 years old
Exclusion criteria:
patients with other diseases related to behcet , crohn disease, rheiter syndrome or any other inflammatory disease using analgesic mouthwash or systemic analgesia since 3 days ago pregnant women

Age
From **6 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **22**

Randomization (investigator's opinion)
Randomized

Randomization description
simple randomization Unit of randomization is individual Tools used in randomization is flipping a coin. head is considered as control and tail as intervention group. allocation concealment is carring out

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Mehr street, Ghasrdasht Ave.
City
Shiraz
Province
Fars
Postal code
71959-44315

Approval date
2017-10-18, 1396/07/26

Ethics committee reference number
IR.SUMS.REC.1396.121

Health conditions studied

1

Description of health condition studied
recurrent aphtus stomatitis

ICD-10 code
K12.0

ICD-10 code description
Recurrent oral aphthae

Primary outcomes

1

Description
pain intensity

Timepoint
day 0,1,2,3,4,5,6,7

Method of measurement
Visual Analogue Scale

2

Description
oral lesion size

Timepoint
day 0,1,2,3,,4,5,6,7

Method of measurement
measuring with ruler

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In experimental group the patients will receive somaq pills. The patients will use 3pills daily for 7days. By inserting the pill on the lesion, the pill itself will attach to the oral ulcer for some minute. The patient should hold this pill until it solves completely. The pills are 0.9cm in diameter. The pills was prepared by Shiraz Pharmacy Faculty. The compositions of this pill is 50% avicel, 0.2% magnesium Stearate and the remaining is somaq.

Category
Treatment - Drugs

2

Description
Control group: In the control group oral paste triadent 3 times in a day will be used. Teriadent is triamcinolone acetonide 0.1% manufactured by Raha pharma.co, Isfahan, Iran.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shiraz dental school

Full name of responsible person
Fatemeh Lavaee

Street address
Mehr street, Ghasrdasht Ave.

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lavaeef@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Basir Hashemi

Street address
Mehr street, Ghasrdasht Ave.

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Shiraz

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7195944315

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shiraz University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Fatemeh Lavaee

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Fatemeh Lavaee

Position
Associate professo

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
data related to primary outcome of pain level and size of lesion

When the data will become available and for how long
starting 6 months after publication

To whom data/document is available
people working in academic institutions people working in businesses

Under which criteria data/document could be used
Statistical analysis on data is allowed. The applicant should email a request containing his request and the reason of his request. He should introduce himself. the data will send to him.

From where data/document is obtainable
call Dr. Fatemeh Lavaee via lavaeef@sums.ac.ir, fatemeh.lavaee@gmail.com Telephone: 00989177029159

What processes are involved for a request to access data/document
The applicant should email a request containing his request and the reason of his request. He should introduce himself. the data will send to him.

Comments